

SAFETY DATA SHEET

Issuing Date 08-Jan-2013

Revision Date 18-Mar-2016

Revision Number 2



The supplier identified below generated this SDS using the UL SDS template. UL did not test, certify, or approve the substance described in this SDS, and all information in this SDS was provided by the supplier or was reproduced from publically available regulatory data sources. UL makes no representations or warranties regarding the completeness or accuracy of the information in this SDS and disclaims all liability in connection with the use of this information or the substance described in this SDS. The layout, appearance and format of this SDS is © 2014 UL LLC. All rights reserved.

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Diphenhydramine HCl 25mg F.C Pink Mini Tabs

Other means of identification

Synonyms 44-329

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name LNK International Inc.

Supplier Address 22 Arkay Drive
Hauppauge
New York
11788
US

Supplier Phone Number Phone:631-435-3500
Fax:631-435-3542

Supplier Email jhogan@lnkintl.com

Emergency telephone number 1-800-426-9381

2. HAZARDS IDENTIFICATION

Classification

Over-the-counter drugs in their final form as sold to the consumer are exempt from regulation under the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Thus, no SDS is required for this product. The information provided below is a composite of the safety data sheets for the active ingredients and is not intended to comply with any regulatory requirement. It is provided in the form of an SDS at the request of the purchaser.



Precautionary Statements - Storage

Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children

Precautionary Statements - Disposal

Dispose of in accordance with local regulations

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

52.7 % of the mixture consists of ingredient(s) of unknown toxicity

Other information

May be harmful if swallowed

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No	Weight-%	Trade Secret
Maize starch	9005-25-8	15 - 40	*
Microcrystalline cellulose	9004-34-6	10 - 30	*
Dicalcium phosphate dihydrate	7789-77-7	10 - 30	*
Diphenhydramine hydrochloride	147-24-0	5 - 10	*
Silicon dioxide	7631-86-9	3 - 7	*
Titanium dioxide	13463-67-7	1 - 5	*
D&C red #27 aluminum lake	15876-58-1	1 - 5	*
Magnesium stearate	557-04-0	0.1 - 1	*
Polyethylene glycol	25322-68-3	1 - 5	*
Polyvinyl alcohol	9002-89-5	1 - 5	*
Stearic acid	57-11-4	5 - 15	*
Talc	14807-96-6	1 - 5	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES

First aid measures**General Advice**

Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away. Immediate medical attention is required.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Skin contact

Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Inhalation

Remove to fresh air. If symptoms persist, call a physician.



Ingestion If swallowed above therapeutic dose: Rinse mouth. Drink plenty of water. Do NOT induce vomiting. If symptoms persist, call a physician. If large quantities of this material are swallowed, call a physician immediately.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects Burning sensation.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

No information available.

Uniform Fire Code Irritant: Solid

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA	Health Hazard 2	Flammability 0	Stability 0	Physical and Chemical Hazards -
-------------	------------------------	-----------------------	--------------------	--

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Store in original container.

Incompatible Products Strong acids. Strong oxidizing agents. Strong bases.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines The following addresses exposure to some of the ingredients of Diphenhydramine HCl 25mg F.C Pink Mini Tabs, not exposure to the product. For information regarding appropriate use of the product, review the labeling and packaging material.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Maize starch 9005-25-8	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust
Microcrystalline cellulose	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust	TWA: 10 mg/m ³ total dust



9004-34-6		TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 5 mg/m ³ respirable dust
Silicon dioxide 7631-86-9	10 mg/m ³	20 mppcf TWA; ((80)/(%) SiO ₂) mg/m ³)	IDLH: 3000 mg/m ³ TWA: 6 mg/m ³
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits NIOSH IDLH Immediately Dangerous to Life or Health

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin and body protection Wear protective gloves and protective clothing. Long sleeved clothing. Impervious gloves.

Respiratory protection If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Solid/Powder, Solid	Odor	Odorless
Appearance	Varies	Odor Threshold	No information available
Color	No information available		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No data available	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	



Vapor density	No data available	None known
Specific Gravity	No data available	None known
Water Solubility	Soluble in hot water	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water		None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity		None known
Explosive properties	No data available	
Oxidizing properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong acids. Strong oxidizing agents. Strong bases.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure**Product Information**

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components). Prolonged contact may cause redness and irritation.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline cellulose 9004-34-6	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
Diphenhydramine hydrochloride 147-24-0	= 500 mg/kg (Rat)	-	-
Silicon dioxide 7631-86-9	> 5000 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 2.2 mg/L (Rat) 1 h
Titanium dioxide 13463-67-7	> 10000 mg/kg (Rat)	-	-

Information on toxicological effects

Symptoms Erythema (skin redness). May cause redness and tearing of the eyes.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

Chemical name	ACGIH	IARC	NTP	OSHA
Silicon dioxide 7631-86-9		Group 3		
Titanium dioxide 13463-67-7		Group 2B		X

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Chronic Toxicity No known effect based on information supplied.

Target Organ Effects Eyes. Lungs. Respiratory system. Skin. Gastrointestinal tract (GI).

Aspiration Hazard No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)

2,216.00 mg/kg



12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Silicon dioxide 7631-86-9	72h EC50: = 440 mg/L (Pseudokirchneriella subcapitata)	96h LC50: = 5000 mg/L (Brachydanio rerio)		48h EC50: = 7600 mg/L

Persistence and Degradability

No information available.

Bioaccumulation

No information available

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 311

14. TRANSPORT INFORMATION

<u>DOT</u>	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A

<u>TDG</u>	Not regulated
------------	---------------

<u>MEX</u>	Not regulated
------------	---------------

<u>ICAO</u>	Not regulated
-------------	---------------

<u>IATA</u>	Not regulated
Proper Shipping Name	NON REGULATED



Hazard Class	N/A
IMDG/IMO	Not regulated
Hazard Class	N/A
Marine Pollutant	Product is a marine pollutant according to the criteria set by IMDG/IMO
RID	Not regulated
ADR	Not regulated
ADN	Not regulated

15. REGULATORY INFORMATION

Regulatory status

Over-the-counter drugs in their final form as sold to the consumer are exempt from regulation under the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Thus, no SDS is required for this product. The information provided below is a composite of the SD sheets for the active ingredients and is not intended to comply with any regulatory requirement. It is provided in the form of an SDS at the request of the purchaser.

International Inventories

TSCA Complies
 DSL All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.



Chemical name	California Proposition 65
Titanium dioxide - 13463-67-7	Carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Maize starch 9005-25-8		X	X		
Titanium dioxide 13463-67-7	X	X	X		
Talc 14807-96-6	X	X	X		

International Regulations**Mexico****National occupational exposure limits**

Component	Carcinogen Status	Exposure Limits
Microcrystalline cellulose 9004-34-6 (10 - 30)		Mexico: TWA 10 mg/m ³ Mexico: STEL 20 mg/m ³
Titanium dioxide 13463-67-7 (1 - 5)		Mexico: TWA= 10 mg/m ³ Mexico: STEL= 20 mg/m ³

*Mexico - Occupational Exposure Limits - Carcinogens***Canada****WHMIS Hazard Class**

Not determined

16. OTHER INFORMATION

NFPA	Health Hazards 2	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 2	Flammability 0	Physical Hazard 0	Personal Protection X

Prepared By Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Issuing Date 08-Jan-2013
Revision Date 18-Mar-2016
Revision Note No information available

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet